Main book

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DEPARTMENT OF HEALTH AND WELFARE
Division of Medicaid

BUREAU OF FACILITY STANDARDS

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INFORMATIONAL LETTER #99-25

DATE: September 30, 1999

TO: ALL HOSPITAL PROVIDERS

FROM: JOHN W. HATHAWAY, Chief
Bureau of Facility Standards

SUBJECT: **NEW HOSPITAL CONDITION OF PARTICIPATION: PATIENT RIGHTS**

Enclosed are the new condition and standards found in 42 CFR §482.13, Condition of Participation: Patient Rights, published in the July 2, 1999, Federal Register.

This new Condition of Participation covers notice of rights, exercise of rights, privacy and safety, confidentiality of patient records, and seclusion and restraints. These requirements became a part of the survey process for all hospitals, except Critical Access Hospitals (CAHs), beginning August 2, 1999. The requirements will not be a part of the survey process for currently certified CAHs. Hospitals requesting CAH status, who are not yet certified as a CAH, must be in compliance with all Medicare Hospital Conditions of Participation at the time of their initial CAH survey. This includes compliance with the Condition of Participation of Patient Rights.

If you have questions regarding the enclosed documents, please contact Gary Guiles, Health Facility Surveyor, or Sylvia Creswell, Supervisor, Non-Long Term Care, at our offices in Boise at (208) 334-6626.

John W. Hathaway

JOHN W. HATHAWAY, Chief
Bureau of Facility Standards

JWH/nah
Enclosures
cc: Idaho Hospital Association

receive care in a safe setting free from verbal or physical abuse or harassment; (8) confidentiality of his or her clinical records and the ability to access information contained in his or her clinical records within a reasonable time frame; and (9) be free from restraints and seclusion of any form used as a means of coercion discipline convenience, or retaliation by staff.

The burden associated with this requirement is the time and effort necessary to disclose the notice requirements referenced above to each patient. We estimate that on average it will take each of the 6,097 estimated hospitals 8 hours to develop the required notice and that it will take each hospital 5 minutes to provide each notice, with an average of 5,515 notices provided per hospital on an annual basis. Therefore, the total annual burden associated with this requirement is 2,850,801 hours.

In its resolution of the grievance, a hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each hospital 15 minutes to develop and disseminate the required notice. We further estimate that 6,097 hospitals will provide 55 notices on an annual basis, a total annual burden of 83,834 hours.

Hospitals will have to report to HCFA through the appropriate HCFA regional office, any deaths that result from restraint or seclusion use for behavior management. The burden associated with this requirement is for hospitals to notify HCFA, via telephone call, of any deaths. Based upon current data, we estimate the number of reports to average less than 10 calls on an annual basis. Therefore, this requirement is not subject to the PRA, as defined under 5 CFR 1320.3(c).

Hospitals must maintain documentation that each of the standards and related requirements referenced in this regulation have been met. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and 1320.3(b)(3) because this requirement is considered a usual and customary business practice; is required under State or local law; and is used to satisfy accreditation requirements.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in § 482.13. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and recordkeeping requirements, please mail the original and three copies directly to the following:

Health Care Financing Administration
Office of Information Services,
Standards and Security Group
Division of HCFA Enterprise
Standards, Room N2-14-26, 7500
Security Boulevard, Baltimore, MD
21244-1850 Attn: John Burke HCFA-3018-IFC.

and

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Attn: Allison Eydt, HCFA Desk
Officer.

List of Subjects in 42 CFR Part 482

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR chapter IV, part 482 is amended as follows:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

Subpart B—Administration

2. Section 482.13 is added to subpart B to read as follows:

§ 482.13 Condition of participation: Patients' rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Peer Review Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not

frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) *Standard: Restraint for acute medical and surgical care.* (1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint must be—

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—

(A) Never be written as a standing or on an as needed basis (that is, PRN); and

(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

(f) *Standard: Seclusion and restraint for behavior management.* (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term "restraint" includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

(7) The hospital must report to HCFA any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare Hospital Insurance; Program No. 93.778, Medical Assistance Program)

Dated: May 24, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: June 9, 1999.

Donna E. Shalala,

Secretary.

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